Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigation of the effects of dextrose saline on the reduction of post operation nausia and vomiting(PONV) after orthopedic surgery

Protocol summary

Summary

This is a single-centered, double-blinded randomized clinical trial which compares the efficacy of the administration of (dextrose saline) and (normal saline) before anesthesia, on the frequency of postoperation nausea and vomiting in patients who undergo orthopedic surgery with general anesthesia. individuals take part in the study who are at the range of18-65 years, in class of I and II of "ASA Physical Status Classification", and candidates of elective orthopedic surgery which lasts more than 2 hours. written informed consent is obtained of all participants.all individuals in the study, at the time of surgery, must have normal blood glucose levels , not having nausea and have not taken anti-emetic drugs. people with abnormal blood glucose levels at the time of surgery or with the severe intraoperative hypotension will be excluded from the study.Allocation of patients into two groups are based on the table of random numbers. individuals of the first group_ as the intervention group_ receive dextrose saline, and second group_as the control group_ receive Normal saline at the begining of surgery. Nausea and vomiting will be measured and recorded by nurses at 30min, 60min, 120min and 24 hours after admission to the ward, based PNOV criteria. The recovery time will be recorded in both groups. Finally, the data are analyzed and compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015121225481N1**
Registration date: **2016-02-26, 1394/12/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-02-26, 1394/12/07

Registrant information

Name
Farzad Hayati
Name of organization / entity
Tehran University
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Iran (Islamic Republic of)
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Email address
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Recruitment status

Recruitment complete

Funding source

vice chancellor for reseach ,Mashhad University of Medical Sciences

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2015-03-21, 1394/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effects of dextrose saline on the reduction of post operation nausia and vomiting(PONV) after orthopedic surgery

Public title

Investigation the effect of dextrose saline on the reduction of post operation nausea and vomiting (PONV)

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria : • Age between 18 and 65 years undergoing orthopedic surgery • ASA class I and II exclusion criteria : • high blood pressure (severe) • liver or kidney disease •coagulopathy • Diabetes • Abnormal blood sugar on the morning of the day of surgery • severe hypotension during surgery that requires intravenous administration of large volumes • Lack of consent to participate in the study have

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **310**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Mashhad University of Medical Sciences,Pardisan

City

Mashhad

Postal code

Approval date

2013-08-20, 1392/05/29

Ethics committee reference number

930088

Health conditions studied

1

Description of health condition studied

Postoperative Nausea and Vomiting

ICD-10 code

T88.7

ICD-10 code description

Unspecified adverse effect of drug or medicament

Primary outcomes

1

Description

severity of Postoperative Nausea and Vomiting

Timepoint

nausea and vomiting PNOV criteria at 30, 60, 120 minutes and 24 hours after ward admission

Method of measurement

It will be measured based on a verbal descriptive scalewhich is related with a visual analog nausea score.

Secondary outcomes

1

Description

recovery time

Timepoint

based on the time of patients' recovery time it will be different

Method of measurement

The time it takes after the surgery to the patient's recovery (in terms of minutes or hours)

Intervention groups

1

Description

In the control group: normal saline is used alone. All subjects received general anesthesia using midazolam(0.1mg/kg) propofol (2– 2.5 mg/kg)for induction and fentanyl 2µ/kg for analgesia and volatile anesthesia for maintenance.All patients were monitored by (blood pressure, pulse, oxygen saturation of arterial blood, electrocardiogram) .

Category

Treatment - Drugs

2

Description

In the intervention group: a combination of (5% dextrose and normal saline) were used. Infusion controlled by infusion pumps at 125 mL/h IV for 2 hours (250 mL) beginning with the start of surgical closure. This volume was chosen to provide small glucose supplements, and blood glucose increases after infusion.All subjects received general anesthesia using midazolam(0.1mg/kg) propofol (2– 2.5 mg/kg)for induction and fentanyl 2µ/kg for analgesia and volatile anesthesia for maintenance.All patients were monitored by (blood pressure, pulse, oxygen saturation of arterial blood, electrocardiogram) .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
Street address
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Mashhad University of Medical Sciences
Full name of responsible person
Reza Jallaiyan Taghadomi
Street address
Ghaem Hospital, Ahmad abad street, Mashhad
City
Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research of Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Farzaneh Fazeli
Position
Anesthesia resident
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Person responsible for scientific inquiries

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Reza Jallaiyan Taghadomi
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Associate Professor of Mashhad University of Medical Sciences
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Web page address

Person responsible for updating data

Contact
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Full name of responsible person
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Postal code
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+98 51 3761 0860
Fax
Email
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty

Analytic Code

empty

Data Dictionary

empty